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510(k) Summary

Contact Name: Lucian Popescu, QA Manager

Trade Name – RamSoft PACS

Common Name – Picture Archiving and Communication System (PACS)

Classification Name - LLZ – Image Processing System (892.2050)

Substantially Equivalent devices:

Ultrapro 98 (RamSoft Inc) – K982563

Kodak AutoRad (Kodak) – K955092

GE Advantage (General Electric Medical Systems) – K94120

Description:

RamSoft PACS is a stand-alone software package that is used on general purpose computing hardware. As long as minimum hardware requirements are met, the user or system integrator is free to choose his/her own hardware platform.

The software allows digital image processing, measurement, communication, and storage.

RamSoft PACS is tested according to the specifications that are documented in a RamSoft PACS System Test Plan. Testing is an integral part of RamSoft's software development process.

The software does not contact the patient, nor does it control any life-sustaining devices. A physician has ample opportunity for competent human intervention while interpreting images and clinical information.

Intended Use:

RamSoft PACS software is used with general purpose computing hardware to acquire, transmit, store and display images for clinical purposes. RamSoft PACS consists of one or more of image server, web server, database server, and workstations for interpretation, clinical review, quality control, video capturing, film digitizing, document scanning. Images may be acquired from imaging devices such as CR, CT, DX, MR, NM, PT, RF, US, XA, and other devices.

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Comparison to Predicate Devices

Product Name	GE Advantage Windows (K942120)	Kodak AutoRad (K955092)	RamSoft Ultrapro 98 K982563	RamSoft PACS (this submission)
Print to paper	Yes	Yes	Yes	Yes
Graphical UI	Yes	Yes	Yes	Yes
Windows OS	Yes	Yes	Yes	Yes
Uses standard displays	Yes	Yes	Yes	Yes
Image input	DICOM 3.0	DICOM 3.0	DICOM 3.0 Bitmap JPEG TIFF Film Video TWAIN	DICOM 3.0 Bitmap JPEG TIFF Film Video TWAIN
Images stored on remote NT server	Yes	Yes	Yes	Yes
Network protocol	TCP/IP	TCP/IP	TCP/IP	TCP/IP
Compression	Wavelet	JPEG	JPEG RLE	JPEG RLE
Annotation	Yes	Yes	Yes	Yes
Image Measurement	Yes	No	Yes	Yes
Cine tool	Yes	Yes	Yes	Yes
Comparison Mode	Yes	Yes	Yes	Yes
Review RIS Report	Yes	Yes	Yes	Yes
Designed for use inside and outside radiology	Yes	Yes	Yes	Yes
Flip/Rotate images	Yes	Yes	Yes	Yes
User Log in	Yes	Yes	Yes	Yes
Multiple layout options	Yes	Yes	Yes	Yes
Window control and presets	Yes	Yes	Yes	Yes
Patient and Study Browser	Yes	Yes	Yes	Yes
MPR	Yes	No	No	Yes
MIP	Yes	No	No	Yes

Conclusion

In conclusion, RamSoft PACS is substantially equivalent to RamSoft Ultrapro 98, GE Advantage, and Kodak AutoRad. The determination of substantial equivalence is not based on an assessment of performance tests. It is our conclusion that there is no software component in RamSoft PACS product or hardware component which would be used in conjunction with RamSoft PACS product that we know of whose failure or latent design flaw would be expected to result in death or injury to a patient. Thus, the "Level of Concern" of RamSoft PACS product is "minor."

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 1 2003

Mr. Lucian Popescu
QA Manager
RamSoft, Inc.
215-16 Four Seasons Place
Toronto, ON M9B 6E5
CANADA

Re: K031562
Trade/Device Name: RamSoft PACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: May 16, 2003
Received: May 21, 2003

Dear Mr. Popescu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K031562

Device Name: RamSoft PACS

Indications for Use:

RamSoft PACS software is used with general purpose computing hardware to acquire, transmit, store and display images for clinical purposes. RamSoft PACS consists of one or more of image server, web server, database server, and workstations for interpretation, clinical review, quality control, video capturing, film digitizing, document scanning. Images may be acquired from imaging devices such as CR, CT, DX, MR, NM, PT, RF, US, XA, and other devices.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X -OR- Over-The-Counter Use _____

David A. Legmon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031562